

HOUSE No. 2771

By Mr. DeLeo of Winthrop, petition of Robert A. DeLeo and others relative to the Division of Medical Assistance. Health Care Financing.

The Commonwealth of Massachusetts

PETITION OF:

Robert A. DeLeo	Kay Khan
Christine E. Canavan	Patricia D. Jehlen
Michael E. Festa	Mary E. Grant
Anne M. Gobi	Frank I. Smizik
Shirley Gomes	Colleen M. Garry
Louis L. Kafka	Deborah D. Blumer
Eugene L. O'Flaherty	Cory Atkins
Douglas W. Petersen	Kevin G. Honan
Timothy J. Toomey, Jr.	John W. Scibak
Dianne Wilkerson	Kathi-Anne Reinstein

In the Year Two Thousand and Five.

AN ACT RELATIVE TO THE DIVISION OF MEDICAL ASSISTANCE.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Section 17 of Chapter 118E of the General Laws,
2 as appearing in the 2002 Official Edition, is hereby amended by
3 striking the words “provision of written documentation by the
4 practitioner to the division that” and inserting in place thereof:—
5 “provisions of section 53 of this chapter and”.

1 SECTION 2. Chapter 118E of the General Laws, as appearing
2 in the 2002 Official Edition, is hereby amended by adding at the
3 end thereof the following new section:—

4 Section 53. Drug prior authorization process.

5 (a) The Division shall administer a drug prior authorization
6 process to ensure the timely dispensing of drugs, for any out-

7 patient prescription drug. In administering said process the Divi-
8 sion shall meet the following conditions:

9 (1) Provide telephone, fax or other electronically transmitted
10 approval or denial within twenty-four (24) hours after receipt of
11 the prior authorization request;

12 (2) If in the prescribing physician's opinion an emergency situ-
13 ation exists, including a situation in which a response to a prior
14 authorization request is unavailable, allow for the prescribed drug
15 to be dispensed at a physician's discretion and until such time as
16 the prior authorization process and subsequent appeals are deter-
17 mined. Any drug dispensed in said manner shall be eligible for
18 full coverage and payment by the Division of Medical Assistance;

19 (3) Grant authorization of drugs prescribed for a medically
20 accepted use supported by either approved product labeling or
21 peer reviewed literature unless there is a therapeutically equiva-
22 lent generic drug that is available without prior authorization;

23 (4) Allow any patient that receives benefits under a program of
24 the division, and is receiving maintenance medications for a
25 chronic illness, to receive said medications until the existing pre-
26 scription expires, or for a period not to exceed six months,
27 whichever is greater, without the need for any prior approvals to
28 be granted.

29 (5) Consult with the Pharmacy and Therapeutics Advisory
30 Committee, established in Section 3 of this act, to develop and
31 implement improvements to the drug prior authorization process
32 and make a report to the advisory committee on the status of the
33 prior authorization list and any changes, related hearings or other
34 proceedings semi-annually.

35 (b) The division shall maintain a process for the evaluation of
36 drugs to be placed on the prior authorization list, which shall
37 include:

38 (1) A public hearing on all medications prior to a decision
39 being made on prior authorization;

40 (2) publishing conspicuous notice in at least one newspaper of
41 general circulation and on the division's website at least thirty
42 (30) days prior to any public hearing on whether such a drug
43 should be placed on prior authorization;

44 (3) consideration of any information provided by any interested
45 party, including but not limited to physicians, pharmacists, benefi-
46 ciaries, and manufacturers or distributors of the drug;

47 (4) consideration of the potential impact on patient care, safety
48 and other sectors of the state health care systems including emer-
49 gency room visits and hospitalizations as a result of placement of
50 such drug on prior authorization;

51 (5) receipt of written approval by a physician who is board cer-
52 tified in the specialty that most commonly treats the disease or
53 prescribes the relevant therapeutic class of drugs. Said physician
54 shall not be employed by, nor have any financial relationship with,
55 any pharmacy benefits management company managing Medicaid
56 prescription benefits, nor be a member of the Pharmacy and Ther-
57 apeutics Advisory Committee. Such written ratification shall be
58 submitted to the commissioner, members of the Pharmacy and
59 Therapeutics Advisory Committee, and shall be available to the
60 public upon request; and,

61 (6) A final decision shall be made within 60 days of the public
62 hearing and published for public comment for a period of no less
63 than 30 days. The effective date of the decision shall not be prior
64 to the close of the comment period and effective notice of the
65 decision's finality is available to prescribers.

66 (c) Notwithstanding any other provision of this section, no drug
67 shall be recommended to require prior authorization by the divi-
68 sion and placed on prior authorization, which has been approved
69 or had any of its particular uses approved by the FDA under a pri-
70 ority review classification;

71 (d) The Division shall develop a grievance mechanism for
72 interested parties to appeal the Department's decision to place a
73 drug on prior authorization, which at a minimum shall be con-
74 cluded within ten days. After participating in the grievance mech-
75 anism developed by the Department on the recommendations of
76 the advisory committee, any interested party aggrieved by the
77 placement of a drug on prior authorization shall be entitled to an
78 administrative hearing before the Department;

79 (e) The Division shall review the prior authorization status of a
80 drug annually;

81 (f) The Division shall make a report to the house and senate
82 committees on ways and means and the house and senate commit-
83 tees on health care at the conclusion of all prior authorization pro-
84 ceedings for each therapeutic class or at least, no less often than
85 annually. Said report shall include but not be limited to the out-

86 comes of all public hearings and prior authorization decisions; a
87 list of drugs which are and are not to be prior authorized along
88 with corresponding information used to make such decisions; sec-
89 tors of the state health care program that may be affected by the
90 drug's availability for use in treating program beneficiaries; any
91 changes made or proposed to the prior authorization process; and
92 recommendations including legislation that may benefit the prior
93 authorization process and program beneficiaries; said report shall
94 be posted on the division's website.

1 SECTION 3. Chapter 118E of the General Laws, as appearing
2 in the 2002 Official Edition, is hereby amended by adding at the
3 end thereof the following new section:—

4 Section 54. Pharmacy and Therapeutics Advisory Committee.

5 (a) There is hereby established a Pharmacy and Therapeutics
6 Advisory Committee for the purpose of advising and making rec-
7 ommendations to the Division of Medical Assistance's prior
8 authorization program. Said advisory committee shall consist of
9 thirteen (13) members to be appointed by the Governor and shall
10 include: five physicians licensed in Massachusetts and actively
11 involved in the practice of medicine; three pharmacists licensed to
12 do business in the commonwealth and actively involved in the
13 practice of pharmacy; a representative of the Massachusetts Med-
14 ical Society; a representative of the Massachusetts Pharmacy
15 Association; a representative of medical assistance beneficiaries
16 in the commonwealth; and, two patient advocates.

17 In making physician appointments the Governor shall make his
18 selections from a list of nominees provided by the Massachusetts
19 Medical Society. In making pharmacist appointments the Gov-
20 ernor shall make his selections from a list of nominees provided
21 by the Massachusetts Pharmacy Association.

22 Advisory committee members shall serve staggered three-year
23 terms. Two physicians, one pharmacist and the representative of
24 medical assistance beneficiaries shall each be appointed for one-
25 year terms. Members may be reappointed for a period not to
26 exceed three, three-year terms. Advisory committee members
27 shall select a chairperson and a vice-chairperson by a majority
28 vote of the committee membership on an annual basis. Said com-
29 mittee shall meet at least monthly and may meet at other times at

30 the discretion of the chairperson. Notice of any meeting of the
31 advisory committee shall be published thirty (30) days before
32 such meeting; and

33 (b) The advisory committee shall have the power and duty to:

34 (1) advise and make recommendations regarding the implemen-
35 tation of a drug prior authorization program for the medical assis-
36 tance program;

37 (2) advise and make recommendations regarding rules to be
38 promulgated by the division regarding outpatient prescription
39 drug prior authorization;

40 (3) make recommendations for a grievance mechanism for
41 interested parties to appeal any decision made by the Division to
42 place a drug on prior authorization;

43 (4) make recommendations to the Division regarding any inpa-
44 tient or outpatient prescription drug covered by the medical assis-
45 tance program that is to be prior authorized as well as which drugs
46 are exempt from the prior approval process. Said recommendation
47 shall be supported by an analysis of prospective and retrospective
48 DUR data demonstrating:

49 (a) the expected impact of such a decision on the clinical care
50 likely to be received by beneficiaries for whom the drug is med-
51 ically necessary;

52 (b) the expected impact on physicians whose patients require
53 the drug;

54 (c) the expected fiscal impact on the medical assistance pro-
55 gram;

56 (d) review and make recommendations on a semi-annual basis
57 whether drugs placed on prior authorization should remain on
58 prior authorization; and

59 (e) make recommendations for a list of maintenance medica-
60 tions that are needed for chronic illnesses;